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EXAMINER	
REDDIG, PETER J	

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 11/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/813,412	CHAN-HUI ET AL.	
	Examiner	Art Unit	
	Peter J. Reddig	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 August 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12* is/are pending in the application.

4a) Of the above claim(s) *1-7* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *8-12* is/are rejected.

7)☒ Claim(s) *8* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *30 March 2004* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *8/30/04; 8/23/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. The response filed on August 30, 2006 to the restriction requirement of May 30, 2006 has been received. Applicant has elected Group II, claims 8-12 for examination without traverse.

2. Upon review and reconsideration, it is found that the instantly claimed invention contains claims drawn to the following additional distinct species:

A. Claim 8 is generic to the following disclosed patentably distinct species of Her receptor heterodimers that is inhibited:

1) Her2-Her1

2) Her2-Her3

3) Her2-Her4

B. Claim 1 is generic to the following disclosed patentably distinct species of ErbB-dimer acing drugs:

1) 4D4 Mab

2) Trastuzumab (Herceptin)

3) 2C4 (Omnitarg)

4) GW572016

The above species are independent or distinct because they comprise structurally distinct molecules and have different modes of operation and different effects. Further, each species would require different searches and the consideration of different patentability issues.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an

allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

3. During a telephone conversation with H. Thomas Anderton, Jr. on September 21, 2006 a provisional election was made without traverse to prosecute the invention of Group II, claims 8-12 drawn to the species Her2-Her1 and Trastuzumab (Herceptin). Affirmation of this election must be made by applicant in replying to this Office action.

4. Claims 1-12 are pending.

5. Claims 1-6 have also been withdrawn from further consideration by the examiner under 37 CFR 1.142(b) as being drawn to non-elected inventions.

6. Claims 8-12 as drawn to the Her receptor heterodimers Her2-Her3 and Her2-Her4 and as drawn to the dimer acting-drugs 4D4 Mab, 2C4 (Omnitarg), and GW572016 are hereby withdrawn from further consideration by the examiner under 37 CFR 1.142(b) as being drawn to a non-elected invention.

7. Claims 8-12 as drawn to the Her receptor heterodimers Her2-Her1 and as drawn to the dimer acting-drug Trastuzumab (Herceptin) are currently under consideration.

Specification

8. The abstract of the disclosure is objected to because it exceeds the maximum length of 150 words. Correction is required. See MPEP § 608.01(b) and CFR § 1.72.

9. The specification on page 1 should be amended to reflect the status of the parent application serial number 10/623,057. It should state that U.S. patent application Ser. No. 10/623,057 filed 17 July 2003; now US Patent No.: 7,105,308.

10. The disclosure is objected to because of the following informalities: In the description of Fig. 3C and 3D on p. 38, lines 14-25, the numbers in the specification do not correspond to the numbers in the figures. For example, it appears that the number for the antibody should be 232 not 332 and the number for the agent should be 234 not 334 as depicted in the figure.

Appropriate correction is required of all incorrect numbering.

11. Figures 10A-10C are missing a legend or explanation in the "Brief Description of the Drawings" of the symbols or data points in the graphs. It is unclear what heterodimer each point represents. There is no explanation of these figures in Example 6 on page 54 that refers to these figures.

Appropriate correction is required.

Drawings

12. The drawings are objected to because of following informalities: Figures 5B and 5C are missing the labels for "Normal" and "Tumor" above the middle column of graphs for Her1-Her2 Dimers. Appropriate correction is required.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing

should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Objections

13. Claim 8 is objected to because of the following informalities: The word wherein is repeated on line 3 of the claim. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

14. Claim 12 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 12 recites the phrase "having a cleavage-inducing moiety with an **effective proximity**" and it is unclear what its effective proximity is to. Additionally, the term

"proximity" in claim 12 is a relative term, which renders the claim indefinite. The term "proximity" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The term proximity renders the term effective indefinite. Thus, the metes and bounds of the claim cannot be determined

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

15. Claims 8-12 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are drawn to a method of selecting a patient for treatment of a cancer with the ErbB-dimer-acting drug Trastuzumab, the method comprising the steps of: isolating a patient sample containing cancer cells from a patient, wherein the patient sample is a fixed tissue sample, a frozen tissue sample, or circulating epithelial cells; measuring an amount of the Her receptor heterodimers, Her2/Her1, in the patient sample; comparing each such amount to its corresponding amount from a reference sample; and selecting the patient for treatment with the ErbB dimer-acting drug Trastuzumab whenever an amount of Her2/Her1 heterodimers from the patient sample exceeds the respective corresponding amount from the reference sample.

Factors to be considered in determining whether undue experimentation is required, are summarized in *In re* Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988). There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue." These factors include, but are not limited to:

the breadth of the claims, the nature of the invention, the state of the prior art, the level of one of ordinary skill, the level of predictability in the art, the amount of direction provided by the inventor, the existence of working examples, and the quantity of experimentation needed to make or use the invention based on the content of the disclosure. See also *Ex parte* Forman, 230 USPQ 546 (BPAI 1986).

The specification teaches that the mechanisms of action of many drugs that are in use or are under development require the inhibition of one or more functions of ErbB receptor dimers, such as the association of component receptors into a dimer structure, or a function, such as an enzymatic activity, e.g. kinase activity, or autophosphorylation, that depends on dimerization. The specification teaches that such drugs are referred to herein as "dimer-acting" drugs, or "ErbB dimer-acting" drugs, p. 19, lines 2-6.

The specification teaches that Trastuzumab is a dimer-acting drug, p. 9 lines 8-9. The specification teaches that Her2/Her1 receptor dimers are biomarkers related to Trastuzumab, p. 19, lines 9-10 and Table I and II. The specification teaches that the following references describe the dimer-acting drugs listed in Table II: Traxler, Expert Opin. Ther. Targets, 7: 215-234 (2002) IDS; Baselga, editor, Oncology Biotherapeutics, 2: 1-36 (2002) IDS; Nam et al, Current Drug Targets, 4: 159-179 (2003) IDS; Seymour, Current Drug Targets, 2: 117-133 (2001) IDS.

The specification teaches that using the method of the invention that Her2/Her1 heterodimers were only detected in frozen tissue from breast tumors, not normal breast tissues, see Example 2 and Fig. 5 A-C and Example 10 and Fig. 14A.

The teachings of the specification cannot be extrapolated to the enablement of the claims because the art recognizes that Herceptin is not a Her2/Her1 dimer-acting drug.

In particular, as drawn to Trastuzumab as a Her2/Her1 dimer-acting drug, a review of the references cited above gave no indication that Trastuzumab is a Her2/Her1 dimer-acting drug. Furthermore, Baselga (Cancer Cell, August 2002, 2:93-95, IDS) teaches that "In fact, Herceptin (Trastuzumab) is not capable of inhibiting signaling by ligand-induced ErbB2 (Her2) containing heterodimers, a clearly important mechanism of receptor activation." see p. 94, left column. Furthermore, Baselga teaches that Trastuzumab exerts its antitumor activity by receptor down modulation, prevention of cleavage of the receptor's extracellular domain, and by recruiting the host's immune effector cells, see p. 94, left column. Additionally, Mukherjee et al. (US 2005/0131006 A1 June 16, 2005) teach that, in regard to Herceptin (Trastuzumab) cancer therapy, while the presence of Her2/Her2 homodimers is predictive of responsiveness, the presence of Her heterodimers is predictive of non-responsiveness, see para. 0074. Furthermore, Moulder et al. (Cancer Research, December 15, 2001, 61:8887-8895) teach that induction of cell proliferation in Her2 overexpressing breast cancer cells with the Her1 ligand TGF-alpha (TGF-alpha is a Her1 specific ligand that will stimulate Her1/Her2 heterodimerization in cells expressing Her1 and Her2, see Olayioye et al., EMBO Journal, 2000, 19:3159-3167 [IDS], in particular p. 3160, left column; Fig .1; p. 3162, right column; and Fig. 2) was not inhibited by the addition of saturating concentrations of Herceptin (Trastuzumab), see Fig. 7 and p. 8891, right

column. Additionally, Burgess et al. (Molecular Cell, September, 2003, 12:541-522) teach, based on structural studies of the ErbB family members, that Trastuzumab does not block important sites of receptor-receptor interaction, see p. 550, left column.

Thus, in view of the above, one would not predict that one could select a patient for treatment of a cancer with Trastuzumab based on the Her2/Her1 heterodimer levels in a sample from that patient exceeding the levels of Her2/Her1 heterodimer in a reference sample because the art teaches that Trastuzumab is not a dimer-acting drug. Thus, undue experimentation would be required to demonstrate that Trastuzumab is a dimer-acting drug and that one could use the status of the Her2/Her1 heterodimers in cancer patients as a biomarker for selecting a patients for treatment with Trastuzumab.

Thus one would not predict based solely on the correlation between elevated Her2/Her1 heterodimer expression in breast tumors versus normal tissue, without additional the validation described above, that one would be able to select a patient for treatment of a cancer with Trastuzumab by measuring Her2/Her1 heterodimer levels without undue experimentation.

Applicant is reminded that MPEP 2164.03 teaches "the amount of guidance or direction needed to enable the invention is inversely related to the amount of knowledge in the state of the art as well as the predictability of the art. In re Fisher, 428 F.2d 833, 166 USPQ 18, 24 (CCPA 1970) the amount of guidance or direction refers to that information in the application, as originally filed, that teaches exactly how to make or use the invention. The more that is known in the prior art about the nature of the invention, how to make, and how to use the invention, and the more predictable the art is, the less information needs to be

explicitly state in the specification. In contrast, if little is known in the prior art about the nature of the invention and the art is unpredictable, the specification would need more detail as how to make and use the invention in order for it to be enabling. Given only lack of guidance in the specification, no one skilled in the art would accept the assertion that the claimed invention would function as contemplated or as claimed based only on the information in the specification and that known in the art at the time the invention was made.

The specification provides insufficient guidance with regard to these issues and provides no working examples that would provide guidance to one of skill in the art and for the reasons set forth above, it cannot be predicted that the invention would function as claimed. For the above reasons, undue experimentation would be required to practice the claimed invention.

16. If applicant were able to overcome the rejection set forth above under 35 U.S.C. 112, first paragraph, Claims 8-12 would still be rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of selecting a patient for treatment of **breast cancer** with the ErbB-dimer-acting drug Trastuzumab, the method comprising the steps of: isolating a patient sample containing **breast** cancer cells from a patient, wherein the patient sample is a fixed tissue sample, a frozen tissue sample, or circulating epithelial cells; measuring an amount of the Her receptor heterodimers Her2/Her1 in the patient sample; comparing each such amount to its corresponding amount from a reference sample; and selecting the patient for treatment with the ErbB dimer-acting drug Trastuzumab whenever an amount of Her2/Her1 heterodimers from the patient sample exceeds the respective corresponding amount from the reference sample, does not reasonably provide enablement for a method of selecting a patient for

treatment of a cancer with the ErbB-dimer-acting drug Trastuzumab, the method comprising the steps of: isolating a patient sample containing cancer cells from a patient, wherein the patient sample is a fixed tissue sample, a frozen tissue sample, or circulating epithelial cells; measuring an amount of the Her receptor heterodimers Her2/Her1 in the patient sample; comparing each such amount to its corresponding amount from a reference sample; and selecting the patient for treatment with the ErbB dimer-acting drug Trastuzumab whenever an amount of Her2/Her1 heterodimers from the patient sample exceeds the respective corresponding amount from the reference sample. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The claims are drawn to a method of selecting a patient for treatment of a cancer with the ErbB-dimer-acting drug Trastuzumab, the method comprising the steps of: isolating a patient sample containing cancer cells from a patient, wherein the patient sample is a fixed tissue sample, a frozen tissue sample, or circulating epithelial cells; measuring an amount of the Her receptor heterodimers Her2/Her1 in the patient sample; comparing each such amount to its corresponding amount from a reference sample; and selecting the patient for treatment with the ErbB dimer-acting drug Trastuzumab whenever an amount of Her2/Her1 heterodimers from the patient sample exceeds the respective corresponding amount from the reference sample.

This means that one can select a patient for treatment of **any** cancer with the ErbB-dimer-acting drug Trastuzumab based on the Her2/Her1 heterodimer expression in the patient compared to a reference sample.

The specification teaches that using the method of the invention that Her2/Her1 heterodimers were only detected in frozen tissue from breast tumors, not normal breast tissues, see Example 2 and Fig. 5 A-C and Example 10 and Fig. 14A.

One cannot extrapolate the teachings of the specification to the scope of the claims because the heterogeneity of cancer is well known in the art.

In particular, as drawn to cancer heterogeneity, cancers comprise a broad group of malignant neoplasms divided into two categories, carcinoma and sarcoma. The carcinomas originate in epithelial tissues while sarcomas develop from connective tissues, see Taber's Cyclopedic Medical Dictionary (1985, F.A. Davis Company, Philadelphia, p. 274). Given that not all cancers originate from the same tissue types, it is expected and known that cancers originate from different tissue types have different structures as well as etiologies and would present differently. Thus, it would not be predictably expected that a nexus, for example drawn to a connection between Her2/Her1 heterodimer expression and selecting a patient for Trastuzumab therapy, would be established between two cancer types that arose from different tissue types. Further, it is well known that even two carcinomas that present on the same organ have significant differences in etiology and genetic constitution. For example, Busken, C et al, (Digestive Disease Week Abstracts and Itinerary Planner, 2003, abstract No:850), teach that there is a difference in COX-2 expression with respect to intensity, homogeneity, localization and prognostic significance between adenocarcinoma of the cardia and distal esophagus, suggesting that these two cancers have different etiology and genetic constitution (last five lines of the abstract). Furthermore, Krontiris and Capizzi (Internal Medicine, 4th Edition, Editor-in-chief Jay Stein, Elsevier Science, 1994 Chapters 71-72, pages 699-729) teach that the various

types of cancers have different causative agents, involve different cellular mechanisms, and, consequently, differ in treatment protocols. Chemotherapeutic agents are frequently useful against a specific type of neoplasm and especially with the unpredictability of the art there are no drugs broadly effective against all forms of cancer, see Carter, S. K. et al. Chemotherapy of Cancer; Second edition; John Wiley & Sons : New York, 198 1; appendix C. Given the above, it is clear that it is not possible to predictably extrapolate a correlation between Her2/Her1 heterodimer expression and selecting a patient for Trastuzumab therapy in any tumor type other than breast cancer, based on the information in the specification and known in the art without undue experimentation.

Applicant is reminded that MPEP 2164.03 teaches "the amount of guidance or direction needed to enable the invention is inversely related to the amount of knowledge in the state of the art as well as the predictability of the art. In re Fisher, 428 F.2d 833, 166 USPQ 18, 24 (CCPA 1970) the amount of guidance or direction refers to that information in the application, as originally filed, that teaches exactly how to make or use the invention. The more that is known in the prior art about the nature of the invention, how to make, and how to use the invention, and the more predictable the art is, the less information needs to be explicitly state in the specification. In contrast, if little is known in the prior art about the nature of the invention and the art is unpredictable, the specification would need more detail as how to make and use the invention in order for it to be enabling. Given only lack of guidance in the specification, no one skilled in the art would accept the assertion that the claimed invention would function as contemplated or as claimed based only on the information in the specification and that known in the art at the time the invention was made.

The specification provides insufficient guidance with regard to these issues and provides no working examples that would provide guidance to one of skill in the art and for the reasons set forth above, it cannot be predicted that the invention would function as claimed. For the above reasons, undue experimentation would be required to practice the claimed invention.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi* , 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

17. Claims 8-12 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 16-20 and 23 of copending Application No. 10/813,417.

Although the conflicting claims are not identical, they are not patentably distinct from each other because they relate to the same inventive concept. The claims of Application No. 10/813,417 are drawn to method of selecting a patient for treatment of a cancer with one or more

ErbB-dimer-acting drugs, the method comprising the steps of: isolating a patient sample containing cancer cells from a patient; measuring directly in the patient sample an amount of each of one or more ErbB cell surface receptor dimers; comparing each such amount to its corresponding amount from a reference sample; and selecting the patient for treatment with one or more ErbB dimer-acting drugs whenever an amount of one or more cell surface receptor dimers from the patient sample exceeds the respective corresponding amount from the reference sample comprising measuring directly in a patient sample an amount of each of one or more ErbB cell surface receptor complexes in the pending claims. "A generic claim cannot be allowed to an applicant if the prior art discloses a species falling within the claimed genus." The species in that case will anticipate the genus. In re Slayter, 276 F.2d 408, 411, 125 USPQ 345, 347 (CCPA 1960); In re Gosteli, 872 F.2d 1008, 10 USPQ2d 1614 (Fed. Cir. 1989).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

18. Claims 8-12 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 32 and 33 of copending Application No. 10/963,855.

Although the conflicting claims are not identical, they are not patentably distinct from each other because they relate to the same inventive concept. The claims of Application No. 10/963,855 are a method of selecting a patient responsive to one or more pathway-specific drugs, the method comprising the steps of: measuring in a patient sample an amount of each of one or more cell surface receptors, cell surface receptor complexes, signaling complexes, and post-

translational modifications thereof; comparing each such amount to its corresponding amount in a reference sample; and correlating differences in the amounts from the patient sample and the respective corresponding amounts from the reference sample to the responsiveness of the patient to one or more pathway-specific drugs; wherein said one or more cell surface receptors and cell surface receptor complexes are one or more ErbB receptors and ErbB receptor complexes. "A generic claim cannot be allowed to an applicant if the prior art discloses a species falling within the claimed genus." The species in that case will anticipate the genus. In re Slayter, 276 F.2d 408, 411, 125 USPQ 345, 347 (CCPA 1960); In re Gosteli, 872 F.2d 1008, 10 USPQ2d 1614 (Fed. Cir. 1989).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

19. No claims are allowed.

20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Peter J. Reddig whose telephone number is (571) 272-9031. The examiner can normally be reached on M-F 8:30 a.m.-5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on (571) 272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Peter J. Reddig, Ph.D.
Examiner
Art Unit 1642

PJR

SUSAN UNGAR, PH.D
PRIMARY EXAMINER